

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

MDL No. 2804

*THIS DOCUMENT RELATES TO:
ALL CASES*

Case No. 17-md-2804

Hon. Dan Aaron Polster

**NON-PARTY STATE OF OHIO BOARD OF PHARMACY'S
MEMORANDUM IN OPPOSITION McKESSON'S MOTION TO COMPEL**

I. INTRODUCTION

The case presently before the Court concerns federal and state claims brought by Summit and Cuyahoga counties, as well as a number of municipalities located therein, against the manufacturers and distributors of prescription opioid medication. Neither the State of Ohio, nor any of its constituent agencies, is a party to this MDL. The State of Ohio Board of Pharmacy ("Board") has negotiated with McKesson Corporation ("McKesson") in good faith and has provided a substantial number of documents. McKesson and the Board have reached an impasse with McKesson demanding a database that contains the patient records of the overwhelming majority of Ohioans. The Board is forbidden by state and federal law from providing this information, and McKesson has refused to limit its demand to the actual counties at issue or to any reasonable time frame. Indeed, even though this case only involves two counties and municipalities located within them, McKesson has made clear that no such restrictions would satisfy its demands.

In July of last year, McKesson served a subpoena upon the Board seeking, *inter alia*, production of “[a]ll documents reflecting the Board’s receipt of data or information from the Ohio Automated Rx Reporting System (“OARRS”) related to Prescription Opioids.” *See* Ex. A to Mtn. to Compel (emphasis added). It now seeks an order compelling production of something entirely different – the entire OARRS database. Or, put another way, McKesson now seeks unrestricted access to the medical records of every person who has obtained a controlled substance in the State of Ohio since 2006.

McKesson suggests that it is only seeking access to OARRS that all of the Plaintiff entities have. But nothing could be further from the truth. No person or entity has the legal authority to data mine the entire OARRS database in the way that McKesson have proposed. And for good reason. OARRS has records of every controlled substance or “drug of concern” that has been provided to an outpatient since 2005 – roughly 9.5 million patients, including lawyers for the State, prosecutors, police officers, quite likely, federal judges. If a person took a single Valium pill before dental surgery, that record is in OARRS. If a person is having trouble sleeping and has been prescribed Ambien, that person is in OARRS. A transgendered person using a testosterone cream will also be in OARRS.

As McKesson notes in the very first sentence of its motion to compel, this case was brought by two Ohio counties and municipalities which are located within those two counties. Yet McKesson does not ask this Court to compel production of OARRS data limited to those regions, but of the entire state of Ohio. Nor has McKesson limited its request to a specific time period or to specific named individuals. And, even though the case involves opioids, McKesson is not willing to limit the request to only its specific medications or even opioids in general. Instead, it demands full access to everyone’s records without limit. OARRS records transactions

not just maintained for the two named Plaintiff counties – but state-wide. McKesson has not, and indeed cannot, justified such an extraordinary disclosure of protected health information. What relevance to this case is a prescription for three Percocet in Meigs County? Why should McKesson be granted access to the medical records of a child prescribed cough syrup with codeine in Montgomery County? Even if McKesson had offered any justification for the massive intrusion into the medical records of millions of Ohio residents – which it has not – this Court cannot justify such a wide release of such deeply personal medical records.

OARRS records are highly confidential, and access thereto is tightly controlled. *See* Acceptable Use Policies at <https://www.ohiopmp.gov/Documents.aspx>. OARRS was created with a federal grant from the National All Schedules Prescription Electronic Reporting (“NASPER”) Act. In providing this grant money, Congress required states to protect the records from improper access or disclosure. Ohio has done so. *See* Ohio Rev. Code 4729.99(J). The confidentiality and security of data is central to the operation of all prescription drug monitoring programs (“PDMP” or “PMP”). Access to those records should not be granted lightly, and no one should simply be given a copy of the database. OARRS data, in particular, is protected by both state and federal confidentiality provisions. Those provisions are more fully set forth below. In light of McKesson’s plainly deficient request and justification for their demand, this Court need not even reach the merits of McKesson’s argument. But if the Court does, it should allow no access to OARRS or, in the alternative, only that limited access necessary to defend this action.

II. STATEMENT OF FACTS

The Ohio Board of Pharmacy is the State of Ohio’s sole state agency charged with regulating the practice of pharmacy and the legal distribution of drugs. As part of those duties,

the Board licenses and regulates pharmacists, pharmacy interns, pharmacy technicians, and terminal and wholesale distributors of dangerous drugs. *See* Ohio Rev. Code Chapter 4729. In furtherance of those duties, the Board has developed and maintained the OARRS database as a part of Ohio's PDMP.

Though PDMPs existed as far back as the 1970s, development of these databases was strongly encouraged at the federal level through the passage of two federal funding programs.¹ First, in 2002, the Bureau of Justice Assistance, a division of the federal Department of Justice, created the Harold Rogers Prescription Drug Monitoring Grant Program. *See* Pub. L. 107-77; Harold Rogers Prescription Drug Monitoring Program FY 2016 Competitive Grant Announcement, found <https://www.bja.gov/funding/PDMP16.pdf>. Then, in 2005, President Bush signed the NASPER Act into law. Both programs provided funding to states to develop state PDMP databases.

NASPER created a grant program, to be administered by the federal Department of Health and Human Services, to fund the creation of state PDMPs. (Pub. L. No. 109-60). Also in 2005, the Board was directed to create a state PDMP by Ohio Rev. Code 4729.75. Thereafter, the Board began the development and implementation of OARRS.

OARRS consists of two databases. The first is a patient database which contains records of all controlled substances and drugs of concern dispensed to outpatients. The second is an ARCOS-like database which contains records of shipments and deliveries of controlled substances and drugs of concern from wholesalers to retail pharmacies and other end distributors

¹ *See* Thomas Clark et al., *Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices*, The Prescription Drug Monitoring Program Center of Excellence, Heller School for Social Policy and Management, Brandeis University, at 3-4 (2012).

of drugs. These two databases do not currently interact in a way that allows the tracking of a particular drug or pill from a manufacturer to an end user.

The patient database has a public-facing website and is intended to be used by both law enforcement and Board-approved members of the public to ensure compliance with Ohio law. *See* <https://www.ohiopmp.gov/>. In a typical patient database transaction, a patient presents a prescription for a controlled substance to a licensed pharmacist in the state of Ohio. After dispensing that medication, the pharmacist logs the following information into OARRS:

1. Date prescription is filled;
2. Prescription number;
3. Date prescription written;
4. Quantity;
5. Number of refills;
6. Days supply;
7. NDC code;
8. Payment type;
9. Pharmacy name and address;
10. Pharmacy number (assigned by the Board) and Business Activity Codes and Subcodes;
11. Physician name and address;
12. Physician number (assigned by the Board) and Business Activity Codes and Subcodes; and
13. Patient name, sex, address, age, and condition.

Access to the patient database is tightly controlled. No one outside of the OARRS staff at the Board has unfettered access to patient database – not even Board investigators. And no one outside of the Board has access to the wholesaler database.

As discussed in more detail below, limited access to the patient database is granted to pre-approved individuals for specific authorized purposes. *See* Ohio Rev. Code 4729.80(A). Access is granted to specific individuals, not offices or roles. For example, an individual police officer or government agent may be granted an OARRS account in his or her own name for use in connection with his or her own investigation. Agencies or departments do not have a

“universal” account. Nor may anyone granted access use the database for anything other than in connection with a specific case. And the scope of information OARRS makes available to any account holder is limited to only that information which would be appropriate for them to access. In the case of law enforcement officials, for instance, authorization to access an individual’s OARRS data is only granted after entry of a case number and approval for access by their supervisor. *See* Ohio Admin. Code 4729-37-08(B); *State v. Myers*, 27 N.E.3d 895, 899 (Ohio Ct App. 2015). Even then, the official would only have access to the records necessary to complete their investigation.

The same access restrictions are true of any other type of user. Each user’s access is limited to only the type of information necessary to perform their official duties. Amongst those granted access to OARRS are health care professionals who prescribe monitored medications and pharmacists who dispense those medications. Those authorized to access the OARRS database may only do so to the extent necessary. For instance, physicians may only access those records directly related to patients presently under their care or to their own prescribing. Ohio Rev. Code 4729.80(A)(5). Improper access to, or use or distribution of, information contained within the OARRS database is a crime. *See* Ohio Rev. Code 4729.99(J); *Myers*, 27 N.E.3d at 899.

III. ARGUMENT

A. MCKESSON’S MOTION TO COMPEL MUST BE DENIED BECAUSE IT NEVER FORMALLY REQUESTED PRODUCTION OF THE OARRS DATABASE.

McKesson seeks an order compelling the Board to “immediately produce the OARRS database.” McKesson’s motion should fail in the first instance for a very simple reason – it has never before requested production of the OARRS database. As noted above, in its subpoena

duces tecum, McKesson requested only “documents reflecting the Board’s receipt of data or information from the Ohio Automated Rx Reporting System (“OARRS”) related to Prescription Opioids.” (Emphasis added). Federal Rule of Civil Procedure 37 permits a party to seek an order compelling discovery only where a party fails to make a disclosure pursuant to Rule 26. Here, McKesson has never properly made a request for disclosure of the OARRS database itself. It is axiomatic to suggest that the Court cannot compel production of materials McKesson never requested. *See, e.g. Gabel v. Hudson*, Case No. 2:14-cv-1057, 2015 U.S. Dist. LEXIS 145523, at *5 (S.D. Ohio Oct. 27, 2015); *Vanburen v. Ohio Dep’t of Public Safety*, Case No. 2:11-cv-1118, 2013 U.S. Dist. LEXIS , at *10-11 (S.D. Ohio May 10, 2013); *Finisar Corp. v. Cheetah Omni, LLC*, Case No. 11-CV-15625, 2013 U.S. Dist. LEXIS 90, at *14 (E.D. Mich. June 27, 2013). Because McKesson never formally requested production of the OARRS database, its request for compelled production must be denied.

A. 42 U.S.C. § 290DD-2 BARS DISCLOSURE OF SOME OARRS RECORDS.

Even assuming that the Court determines that McKesson properly requested the production of the OARRS database, an unidentifiable number of records is explicitly precluded from disclosure by federal law. Amongst the records contained within OARRS are records of prescriptions for drugs used in the treatment of substance abuse. For instance, two common drugs used in the treatment of substance abuse are the opioids methadone and suboxone. Both are opiates and controlled substances monitored by the OARRS database.² Additionally, medical practitioners frequently prescribe other medications, such as benzodiazepines, to assist in substance abuse treatment. *See* S. Nielsen et al, *Concurrent buprenorphine and benzodiazepines*

² Suboxone (buprenorphine) is a Schedule III controlled substance; Methadone is a Schedule II controlled substance. *See* 21 C.F.R. §§ 1308.12; 1308.13.

use and self-reported opioid toxicity in opioid substitution treatment., ADDICTION, 102(4):616-22 (2007)(two thirds of those using suboxone for substance abuse treatment report concurrent benzodiazepine use). Records of drug treatment are confidential and not subject to disclosure except in very limited circumstances, not applicable here, by operation of 42 U.S.C. § 290dd-2. Violation of this provision is punishable by federal criminal penalties. *See* 42 U.S.C. §290dd-2(f). McKesson explicitly states that it intends to use OARRS data to identify individuals who have been treated for substance abuse. *See* Mtn. to Compel at 13 (PageID 29514). McKesson's fishing expedition is precisely what is prohibited by § 290dd-2.

It is not presently possible within the OARRS database to identify which, if any prescriptions have been ordered for purposes of substance abuse treatment. Most of the drugs used in such treatment, like suboxone and methadone, have alternative uses such as the treatment of pain. And, as explained above, other medications are used in conjunction with methadone and suboxone to treat the underlying causes of drug addiction. It is, therefore, impossible for the Board to accurately extract those records made confidential by 42 U.S.C. § 290dd-2 at this time.

B. STATE AND FEDERAL LAWS PROHIBIT DISCLOSURE OF THE ENTIRE OARRS DATABASE.

McKesson is not entitled to even those records in the database not prohibited from disclosure by § 290dd-2. The millions of people with prescription drug records in OARRS have a right to privacy in that information. *See Whalen v. Roe*, 429 U.S. 589 (1977); *Douglas v. Dobbs*, 419 F.3d 1097, 1102 (10th Cir. 2005). *See also Northwestern Mem. Hosp. v. Ashcroft*, 362 F.3d 923, 928-29 (7th Cir. 2004). The Board has access to this information only because it is fulfilling the important governmental purpose of monitoring the flow of dangerous drugs with the State's borders. To provide access to that same information in connection with a civil suit for

monetary damages would be a gross violation of the privacy rights of millions of people and would interfere with the Board's and other law enforcement agencies' efforts to combat the opioid crisis. This Court should deny McKesson's motion to compel because the OARRS database is confidential by law. But even if the federal and Ohio statutes protecting the confidentiality of the OARRS database are insufficient to warrant protection here, this Court should find that the information contained within the database is privileged within the meaning of Rule 501.

Rule 26(b) permits parties to seek discovery regarding any nonprivileged matter that is relevant to a claim or defense. The Board does not contest that some information contained within the OARRS database is relevant to the case at bar or McKesson's individual defense. Nor does the Board argue that state law confidentiality provisions, standing alone, require this Court to deny the motion to compel. Rather, the Board argues that this Court must engage in a balancing of equities before bypassing those state law provisions. And the balance of equities squarely falls against the disclosure of the entire OARRS database.

Claims of privilege are governed by the common law. FED. R. CIV. PROC. 501. That standard is intended to be flexible, with Courts able to recognize new privileges as they deem necessary. *See United States v. Gillock*, 445 U.S. 360, 367-68 (1980). Here, records contained within the OARRS database are subject to both state law confidentiality and several federally recognized privileges. Even if those provisions were inapplicable, however, this Court should deem information contained within the OARRS database to be privileged because of the strong federal and state interest in the confidentiality of those records.

As noted above, the OARRS database itself is protected by two separate state confidentiality statutes. Reports generated from the database by authorized users are also

separately protected by a panoply of additional confidentiality provisions. Information in OARRS and records of requests for access to that information are confidential and not subject to release. Ohio Rev. Code 4729.80(C). Further, even when information has been lawfully obtained from the database, that information may not be further disclosed or used except in very, very narrow circumstances. *See* Ohio Rev. Code 4729.86. OARRS records are explicitly prohibited by state law from being used in any civil or administrative proceedings. *See* Ohio Rev. Code 4729.86(B). To the extent that OARRS reports have been generated as parts of investigations by various state licensing agencies, those reports are also deemed confidential by law. *See, e.g.,* Ohio Rev. Code 4723.28(I); 4729.23; 4731.22(F)(5). This Court should respect that confidentiality and deny their request for production of the database.

The confidentiality of OARRS data is not simply a creature of state law, but rather the State's expression of a strong federal preference for the confidentiality of PDMP data. Ohio's confidentiality laws were adopted as a condition for federal funding, and should be treated by this Court as enjoying federal support. *See South Dakota v. Dole*, 483 U.S. 203, 206 (1987). From the very beginning, the need to protect the security of the information to be contained in a state PDMP database was well-understood. Indeed, the Supreme Court in *Whalen* devoted an entire paragraph to explaining the security precautions taken by the State of New York in connection with its PDMP. *See Whalen*, 429 U.S. at 593-94, 601. When the federal government decided that it was in the national interest to encourage the development of state PDMPs, security of the information contained therein was an important element of those efforts. NASPER, for instance, specified not only what information should be contained within a state PDMP database, but also that use and disclosure of that information should be limited to approved individuals for proper purposes. *See* Pub. L. No. 109-60 Sec. 399O(f), (g).

Specifically, NASPER required that states seeking funding develop a statutory scheme authorizing release of PDMP database information to: 1) healthcare practitioners “*for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;*” 2) law enforcement personnel only when “*related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;*” 3) another state PDMP; 4) agents of certain specified federal agencies who certify “*that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature;*” 5) state agents charged with the implementation of the PDMP database. *See* Pub. L. No. 109-60 Sec. 399(O)(f) (emphasis added). NASPER also required that States seeking funding from HHS enact legislation imposing penalties for the unauthorized use and disclosure of information retained within a PDMP. *See* Pub. L. 109-60 Sec. 399(O)(a)(2); (c)(2).

Consistent with the requirements set by NASPER, the Ohio General Assembly enacted Ohio Rev. Code 4729.80 to restrict access to the database and information derived therefrom to certain specified classes of individuals. At present, OARRS access is granted to: 1) healthcare practitioners;³ 2) law enforcement and Court personnel;⁴ another state PDMP;⁵ 3) other state agencies required to use prescription data to carry out their designated functions;⁶ 4) an

³ Ohio Rev. Code 4729.80(A)(5), (6), (12), (21); (B)(1), (2).

⁴ Ohio Rev. Code 4729.80(A)(1), (2), (3), (4), (16), (17)

⁵ Ohio Rev. Code 4729.80(A)(14).

⁶ Ohio Rev. Code 4729.80(A)(8), (9), (10), (11).

individual seeking their own records;⁷ 5) peer review committees.⁸ And, as previously noted, improper access to, or distribution of, OARRS data is a crime. As the state law confidentiality provisions applicable to OARRS are mere reflections of the federal prerogative to preserve the confidentiality of state PDMPs, this Court should find that OARRS is privileged and not subject to disclosure.

In support of their motion, McKesson cites cases where, in other contexts, state confidentiality provisions have been denied protection in federal court. In *E.E.O.C. v. Honda of Am. Mfg., Inc.*, No. 2:06-CV-0233, 2006 U.S. Dist. LEXIS 76751 (S.D. Ohio Oct. 12, 2006), the Court denied a motion to quash a subpoena seeking confidential unemployment records retained by the Ohio Department of Jobs and Family Services. That Court did not simply reject the claim of privilege because it rested on state law. Instead, relying on a balancing test used by the same Court in *Freed v. Grand Court Lifestyles, Inc.*, 100 F.Supp. 2d 610 (S.D. Ohio Dec. 21, 1998), the Court found that the “balancing of interests” warranted disclosure of a plaintiff’s unemployment compensation file to her former employer. The rationale for that decision, however, makes clear that its logic does not support McKesson’s position here. In both *Honda* and *Freed*, the defendants sought access to the records of the plaintiff in their respective cases to determine if those plaintiffs had previously made contradictory statements. *See Honda*, 2006 U.S. Dist. LEXIS 76751, at *2; *Freed*, 100 F.Supp.2d at 616-18. In overruling the motion to quash, the *Freed* Court limited what was to be produced to only that information provided by Freed herself. *Freed*, 100 F.Supp. 2d at 617. The Court acknowledged the State’s interest in

⁷ Ohio Rev. Code 4729.80(A)(7), (19).

⁸ Ohio Rev. Code 4729.80(A)(21).

keeping its records confidential and thus limited the required disclosure to only those records directly relevant to the Freed's allegations.

Here, McKesson has offered no individualized request for any record or made any serious attempt to limit the scope of what it has requested to the parts of the OARRS database that are relevant to this case. Instead, it has asked this Court to order the unrestricted disclosure of the entire database, which includes the medical records of millions of Ohio residents. Neither the State of Ohio, nor any individual whose record is contained within OARRS is a party to this action. No Plaintiff in this MDL has ever had the authority to perform the type of analyses on OARRS data that McKesson now seeks to run. Millions of Ohio residents have done nothing warranting disclosure of their medical records. From a child prescribed Ritalin⁹ for ADHD to an individual prescribed Tylenol 3¹⁰ after dental surgery, millions of people who use their prescription medications properly are listed in the OARRS database. This Court should balance their well-acknowledged privacy interest against McKesson's limited interest in conducting a fishing expedition.

C. OARRS IS A LAW ENFORCEMENT DATABASE, AND ITS CONTENTS ARE PROTECTED BY LAW ENFORCEMENT PRIVILEGE.

At its core, the OARRS database is a law enforcement database used by the Board and other law enforcement entities to ensure compliance with Ohio's drug laws. To the extent that access is provided to other authorized individuals, it is only to allow authorized users to ensure that they are in compliance with state law. As a law enforcement database, this Court should hold that the law enforcement privilege bars disclosure of OARRS here.

⁹ Methylphenidate is a Schedule II controlled substance. *See* 21 C.F.R. § 1308.12.

¹⁰ Tylenol 3 is a Schedule III controlled substance. *See* 21 C.F.R. § 1308.13.

The law enforcement privilege is a common law privilege recognized in both state and federal courts. *See Ohio Bureau of Workers Comp. v. MDL Active Duration Fund, Ltd.*, Case No. 2:05-cv-0673, 2006 U.S. Dist. LEXIS 82560, at *9-11 (S.D. Ohio Nov. 13, 2006). The law enforcement privilege applies “when the information sought pertains to sensitive law enforcement techniques and procedures.” *United States v. Garner*, Case No. 3:16-cr-88, 2017 U.S. Dist. LEXIS 44757, at *8 (S.D. Ohio Mar. 27, 2017). Though the Sixth Circuit has not explicitly ruled on the existence of the privilege, both District Courts in this Circuit and the Sixth Circuit Court of Appeals has applied the privilege when law enforcement records are sought. *See, e.g., Goodwin v. City of Cleveland*, Case No. 1:15-cv-0027, 2016 LEXIS 52917, at 3-4 (N.D. Ohio Apr. 20, 2016); *United States v. Quebe*, Case No. 3:15-cv-294, 2017 U.S. Dist. 9005, at 36-37 (S.D. Ohio Jan. 23, 2017); *MDL Active Duration Fund*, 2006 LEXIS 82560. The privilege has been recognized in other circuits. *Id.* (citing cases). The purpose of the law enforcement privilege is “to prevent disclosure of law enforcement techniques and procedures, to preserve the confidentiality of sources, to protect witnesses and law enforcement personnel, to safeguard the privacy of individuals involved in an investigation, and otherwise to prevent interference in an investigation.” *In re Department of Investigation*, 856 F.2d 481, 483 (2nd Cir. 1988). There is a “strong presumption against lifting the privilege.” *Quebe*, 2017 U.S. Dist. LEXIS 9005, at 37.

When considering an assertion of law enforcement privilege, this Court should apply a “balancing approach, weighing the government’s concerns against the need articulated by [McKesson].” *United States v. Pirosko*, 787 F.3d 358, 365 (6th Cir. 2015). Here, the balancing of interests clearly weighs against disclosure of the entire OARRS database. At any time, the OARRS database is being accessed by authorized individuals at numerous governmental

agencies, including federal, state, and local law enforcement agencies, to conduct both criminal and administrative investigations. Some MDL Defendants or their employees have undoubtedly been and may be targets of investigation. McKesson has, as part of their subpoena, requested OARRS access records. Those access records would expose innumerable investigations to many individuals including, but not limited to, targets of investigation themselves. Wholesale disclosure of the entire OARRS database – even with a protective order limiting the further disclosure of the database – will no doubt frustrate efforts by numerous agencies to investigate violations of both state and federal drug laws. Additionally, that same disclosure would violate the well-recognized privacy rights of those individuals who may be targets of investigation.

The primary benefit of collecting all dispensing information state-wide is the ability to identify outliers – individuals who either prescribe or receive more controlled substances than is typical. It is precisely these individuals who McKesson seeks to expose. And it also those individuals who are frequently targets of both criminal and administrative investigations. Allowing McKesson and other MDL parties the unrestricted ability to troll the OARRS database (and presumably use their findings to seek additional evidence or seek to add additional parties to this suit) would no doubt alert targets of criminal and administrative investigations. Even disclosure of the reports generated from OARRS data would ultimately expose the Board's investigative techniques to those who are subject to its supervision.

The Board recognizes that claims of law enforcement privilege must typically be raised with reference to specific investigations that may be compromised. *See Friedman v. Bache Halsey Stuart Shields, Inc.*, 738 F.2d 1336, 1342 (D.C. Cir. 1984). But the sheer breadth and generality of McKesson's request makes such representations difficult. The potential impact on

present investigations by disclosure of the OARRS database to McKesson and other MDL parties, however, cannot be overstated.

Additionally, McKesson can obtain much of the same information from other sources. *See MDL Active Duration Fund*, 2006 LEXIS 82560, at 10 (court must take into account whether material is available from other sources when considering assertion of law enforcement privilege). Here McKesson seeks this Court to order the disclosure of the OARRS database despite the fact that much of the information it seeks is available from other, non-confidential sources. McKesson has not described any other avenues they have taken to attempt to glean the same information from others. The case presently pending before this Court deals with the Cuyahoga and Summit counties and municipalities located therein. McKesson and its co-defendants (including other wholesale distributors and some of the largest retail pharmacy chains in America) have first-hand knowledge of the volume and types of medications they have delivered and dispensed in those regions. Further, the universe of legal dispensers of opioid medications in those regions is limited and a matter of public record. Many, in fact, are employed by the MDL Defendants themselves at retail pharmacy locations throughout the regions addressed by this suit. By way of subpoena, Defendants have access to that information without seeking intervention of this Court. Additionally, prescription records (including information far more detailed than is present in OARRS) could be obtained from the managed care organizations or pharmacy benefit managers licensed in Ohio and operating in the specific regions covered by the present action. In sum, McKesson seeks this Court's extraordinary intervention without offering any explanation as to how it has attempted to obtain the data it seeks from other, non-confidential sources.

McKesson proposes using the database to identify “prescribers who were later accused or convicted of criminal wrongdoing” and “prescriptions filled for patients who were later accused or convicted of criminal wrongdoing.” Mtn. to Compel at 13 (PageID 29514). But McKesson does not need OARRS to find that information. Indeed, OARRS’ patient database would in no way assist it in that search. The patient database does not show whether an individual has been accused or convicted of a crime. Nor would information in the patient database, standing alone, identify individuals who should be charged with a crime. The patient database only tracks the dispensing of drugs to individuals – it does not show whether those drugs were properly dispensed. The decision to prescribe opiate medications lies with the medical practitioner who evaluates a patient. Without the medical records of a specific individual, it is impossible to determine if any specific prescription was even medically improper, let alone criminal. Simply put, it is impossible to derive criminal wrongdoing from the patient database.

If McKesson wants identify people who have been criminally charged or convicted, it can do that by using publicly-available records. As to whether any particular prescription was improper, that information is best obtained from criminal records, state licensure bodies and, perhaps, records of civil suits. To date, the Board, the Ohio Board of Nursing, and the Ohio State Medical Board – the administrative bodies charged with regulating prescribers and dispensers in the state of Ohio – have turned over hundreds of thousands of pages of disciplinary actions taken against licensees for the improper provision of drugs. To the extent that McKesson wishes to identify bad actors, they have more than sufficient data in their possession without resorting to disclosure of OARRS data.

E. THE PUBLIC INTEREST WEIGHS HEAVILY AGAINST DISCLOSURE OF THE OARRS DATABASE.

McKesson simply suggests that “the public interest far outweighs any burden to the Board” when arguing that this Court should order the production of OARRS. *See* Mtn. at 16 (PageID 29517). But it is not only the Board’s interests – which have been explored above - that are being infringed upon by McKesson’s request, but the residents of the State of Ohio. At issue is nothing less than the disclosure of millions of medical records to hundreds, if not thousands, of individuals. The Supreme Court in *Whalen* recognized the privacy implications inherent in the construction of PDMPs and, in affirming the State of New York’s right to collect prescription data, took special care to explain the government’s data security protections. And numerous courts have recognized that individuals have a right to privacy in their prescription records. *See, e.g., Whalen*, 429 U.S. at 599-600; *Dobbs*, 419 F.3d at 1102; *Doe v. Southeastern Pa. Transp. Auth.*, 72 F.3d 1133, 1138 (3d Cir. 1995). McKesson’s interest in obtaining OARRS data cannot overcome the public’s overwhelming interest in maintaining the privacy of their own medical records.

Nor can McKesson overcome the Board’s interest in protecting the sanctity of the database. As previously mentioned, the need for confidentiality of PDMP records has been recognized from the very beginning. Federal grant programs that funded the created of state PDMPs included requirements that states both restrict access to PDMPs and punish those who violate those restrictions. Law enforcement agencies, including the Board, rely on the confidentiality of OARRS records to investigate potential violations without unnecessarily alerting suspects. McKesson has cited no reason compelling enough to overcome those interests in the confidentiality of OARRS.

McKesson invites this Court to treat all of OARRS as it did the federal Automation of Reports and Consolidated Orders System (“ARCOS”). But OARRS is dramatically different from ARCOS. ARCOS contains no patient information. Indeed, ARCOS is merely a repository of inventories and transactions from the manufacturer to the point of sale. The information recorded in ARCOS comes from MDL defendants and other similarly situated entities. No information in ARCOS was entitled to the same privacy protections as the patient and provider information contained in OARRS. This Court, therefore, should not order the disclosure of OARRS simply because the DEA was ordered to provide excerpts of ARCOS data.

F. THE RESEARCH EXTRACTION

As part of its role in monitoring the use of controlled substances in the State of Ohio, and consistent with NASPER’s suggestion to permit access to PDMP data to researchers, the Board has created a de-identified extraction of OARRS data. That “research extraction” is updated every three months and is provided to qualified researchers for use in performing statistical analyses. *See* Ohio Rev. Code 4729.80(C) (permitting disclosure of “information contained in the database that does not identify a person, including any licensee or registrant of the board or other entity.”). The research extraction obscures patient, prescriber, and dispenser names and addresses. Patients, prescribers, and dispensers/pharmacies are instead assigned unique identifiers. Consistent with the practice of the DEA, only the first three digits of zip codes are included in the research extraction. Left unobscured are all other categories of OARRS data.

The Board does not concede that McKesson should be granted access to the de-identified research extraction. Under present Board policy, the research extraction is only available to qualified researchers. And, as previously noted, McKesson could access to much of the data it seeks from OARRS from other sources. But, should the Court determine that disclosure of some

OARRS data is necessary, the Court should order disclosure of the research extraction only. The de-identification process used in creating the extraction mitigates much of the risk associated with the wholesale release of OARRS to MDL parties. It does not contain identifiable patient records. Nor can it be used to discover active law enforcement investigations. What the research extraction can provide is all of the data necessary to perform the analyses suggested by McKesson without violating the privacy rights of millions of people.

CONCLUSION

The Board is cognizant of this Court's desire to speedily resolve this and other related cases. It has opposed McKesson's demand because state and federal law require it to do so. In fact, state and federal law criminalize McKesson's proposal. This Court cannot immunize Board or other state staff from those penalties. And the Board will not hesitate to appeal and seek stay from any order that compels the production of the unredacted data of the residents of Ohio.

But if the Court determines that disclosure of some OARRS data is necessary, it should only order disclosure of the limited information relevant to this case. *See Freed*, 100 F.Supp. 2d at 617. The research extraction described above provides McKesson and other MDL parties all of the data they need to defend this case without unnecessarily exposing the private health information of millions of people. At most, this Court should grant McKesson no more than access to the research extraction for the specific regions of Ohio at issue in this suit. For the above stated reasons, and for any other good cause the Court should discern, the Board requests that the Court deny McKesson's Motion to Compel.

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Respectfully submitted,

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